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SIEMENS

510(k) Summary: Sensis

Company: Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: June 25, 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

Importer / Distributor:
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany

Establishment Registration Number:
3004977335

2. **Contact Person:**
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. **Device Name and Classification:**

Trade Name:	Sensis
Classification Name:	Programmable diagnostic computer
Classification Panel:	Cardiovascular Diagnostic Devices
CFR Section:	21 CFR §870.1425

Device Class:	Class II
Product Code:	DQK
Legally Marketed Predicate Device	
Trade Name:	AXIOM Sensis
510(k) #:	K020440
Clearance Date:	December 3, 2002
Classification Name:	Programmable diagnostic computer
Classification Panel:	Cardiovascular Diagnostic Devices
Classification Regulation:	21 CFR §870.1425
Device Class:	Class II
Product Code:	DQK

4. **Device Description:**
The Sensis Electrophysiological and Hemodynamic Recording System with software VC12 is a further SW and HW development of the commercially available Siemens AXIOM Sensis K020440.

The Sensis is a multi-channel computer-based stationary system for the measurement, display, and printout of bio-physiological events. Hemodynamic and electrophysiological signals such as intracardiac pressure, ECG signals, and intracardiac electrograms (ICEG) are measured and displayed by the system. Sensis software provides the ability to monitor and assess invasive blood pressure, ECG signals, and optionally intracardiac electrograms (ICEG) The user can perform a number of calculations based on manual input and / or on the input signals and other hemodynamic parameter values from the Sensis system.

For more flexibility in the department, additional post processing and reporting workplaces can always be connected to the network.

The software and hardware modification does not affect the intended use of the device nor does it alter its fundamental scientific technology.

5. **Indication for Use:**
The Sensis recording system is intended to be used as a diagnostic and administrative tool supporting hemodynamic cardiac catheterizations and/or intracardiac electrophysiology studies. The system is equipped by modules, enabling various configurations ranging from a stand-alone acquisition unit with limited administrative functionality to multiunit installations with a common database and satellite workstations accessing the data using the administrative tools.

The device is intended to be used on either or both of the following populations:

1. Adult and pediatric populations requiring intracardiac electrophysiology examinations, typically when the patient is suffering from cardiac arrhythmias.
2. Adult and pediatric populations requiring intracardiac hemodynamic examinations, typically when the patient has a heart disease resulting in insufficient hemodynamic functionality.

6. **Substantial Equivalence:**
The Sensis Electrophysiological and Hemodynamic Recording System with software VC12 is substantially equivalent to the commercially available Siemens AXIOM Sensis which was described in premarket notification K020440 which received 510(k) clearance on December 03, 2002.

7. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
The Sensis Electrophysiological and Hemodynamic Recording System with software VC12 is a further SW and HW development of the commercially available Siemens AXIOM Sensis K020440.

The Sensis features the same Indications for use, Acquisition, Monitoring, Recording, Imaging and Administrative Functions as the predicate AXIOM Sensis. It interfaces with Angiograhy X-ray systems e.g. Artis Q, Artis Q zen, Artis zee / zeego. The user function is similar to the predicate AXIOM Sensis device.

8. **Performance Testing:**
Siemens claims conformance to a signed statements of conformance to performance standards. This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) were conducted on the Sensis software during product development. The Risk Analysis was completed and risk control implemented to mitigate identifed hazards. The testing results supports that all software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

EMC/electrical safety was evaluated according to the IEC Standards. Siemens certify to conformance Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. All testing and validation have been completed.

Clinical testing was not applicable as Sensis has no new indications for use nor new clinical applications were introduced to the system.

The Sensis uses the same sensors applied to the patients as the predicate device. These sensors are provided by OEM manufacturer and have their own 510(k) clearances.

All Sensis components do not come into direct contact with patients. For those accessories which come into direct contact with patient, it is ensured that legal manufacturing and supplier provides this biocompatibility and stelilization (where applicable) before integration or use with Sensis. Sensis itself does not have any parts which would require sterilization

9. **General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, and mechanical hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray images.

10. **Conclusion as to Substantial Equivalence:**
The Sensis Electrophysiological and Hemodynamic Recording System with software VC12 is intended for the same indications as cleared in the predicate AXIOM Sensis. The predicate device hardware has 2 PC's. The subject device has only one PC and a nurse workstation with the same functionality as the Sensis PC. It allows a faster, more efficient workflow directly in the examination room.

The functionality of Sensis VC12 is similar to the predicate device. It is Siemens opinion, that the Sensis VC12 is substantially equivalent to the AXIOM Sensis (K020440).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 25, 2013

Siemens Medical Solutions, Inc.
Patricia Jones
51 Valley Stream Parkway
Malven, PA 19355 US

Re: K131812
Trade/Device Name: Sensis and Sensis Lite
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 18, 2013
Received: June 24, 2013

Dear Patricia Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SIEMENS

Special 510(k) Submission: Sensis

Indications for Use Statement

510(k) Number (if known): K131812

Device Name: Sensis

Indications for Use:

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The device is intended to be used on either or both of the following populations:

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2. Adult and pediatric populations requiring intracardiac hemodynamic examinations, typically when the patient has a heart disease resulting in insufficient hemodynamic functionality.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Felipe Aguel
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Concurrence of CDRH; Office of Device Evaluation (ODE)